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510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter:
Ferndale Laboratories, Inc.
780 W. 8 Mile Rd
Ferndale, Michigan 48220
(248) 548-0900

OCT - 9 2009

Contact Person: Richard A. Hamer

Date of Preparation: July28, 2009

II. DEVICE NAME

Proprietary Name: Eletone® Cream

Common Name: Wound Dressing

Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic

III. PREDICATE DEVICES

Sinclair (Atopiclair™) Wound and Skin Emulsion (K024367) Sinclair Pharmaceuticals, Ltd.
MimyX™ Cream (K041342) Stiefel Laboratories, Inc.
Locobase® Wound and Skin Emulsion (Eletone® Cream) (K060272) Ferndale Laboratories, Inc.

IV. DEVICE DESCRIPTION

Eletone® Cream is a semi-viscous emulsion/cream formulation intended for topical application supplied non-sterile in 100g plastic tubes.

V. INTENDED USE

Under the supervision of a healthcare professional, the product is intended for the management and relief of burning, itching and redness associated with various types of dermatoses, including atopic dermatitis, radiation dermatitis and allergic contact dermatitis.

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The product, when applied topically to the affected areas, forms a protective barrier that helps keep the skin moist, which has a beneficial effect on the healing process.

VI. COMPARISON TO PREDICATE DEVICES

Eletone® Cream is identical in composition and function to Locobase® Wound and Skin Emulsion (K060272). Its intended use is identical to other legally marketed wound dressing products, such as Sinclair (Atopiclair™) Wound and Skin Emulsion, Sinclair Pharmaceuticals, Ltd. (K024367), MimyX™ Cream, Stiefel Laboratories, Inc. (K041342). All referenced products are non-sterile emulsions that are applied topically to manage and relieve symptoms of various dermatoses.

VII. CONCLUSION

Functional and performance testing has been conducted to assess the safety and efficacy of Eletone® Cream. Based on the information provided herein, we conclude that the device is substantially equivalent to the above-mentioned predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ferndale Pharma Group, Inc.
% Mr. Richard A. Hamer
VP, Regulatory/Clinical Affairs
Quality Assurance
780 West Eight Mile Road
Ferndale, Michigan 48220

OCT - 9 2009

Re: K092297
Trade/Device Name: Eletone® Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 1, 2009
Received: October 2, 2009

Dear Mr. Hamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K092297

Device Name: Eletone® Cream

Indications For Use: Under the supervision of a healthcare professional, for the management and relief of burning, itching and redness associated with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis, and radiation dermatitis (post-radiation treatment).

Prescription Use __x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krone

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092297